UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MAREK Z. KUBIN, *et al.*,

Appellants.

NOTICE OF APPEAL

Marek Z. Kubin and Raymond G. Goodwin hereby appeal the Decision on Appeal entered on May 31, 2007 and Decision on Request for Rehearing entered on October 24, 2007 by the Board of Patent Appeals and Interferences in Appeal 2007-0819.

The Board of Patent Appeals and Interferences Decision on Appeal was received on May 31, 2007 and the Decision on Request for Rehearing was received on October 24, 2007. This Notice of Appeal complies with the time limits prescribed by 37 C.F.R. § 1.304(a)(1) as it is being filed within two months of the Board of Patent Appeals and Interferences' Decision on Request for Rehearing.

The $450.00 docketing fee required by 28 U.S.C. § 1913 and Federal Circuit Rule 52(a)(3)(A) is submitted herewith.

Date: December 21, 2007

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing **NOTICE OF APPEAL** was served by hand courier on the United States Patent and Trademark Office, on this the 21st day of December, 2007, as follows:

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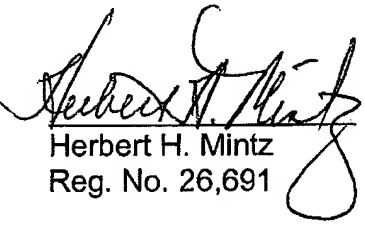
By: 
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PRECEDENTIAL OPINION

Pursuant to the Board of Patent Appeals and Interference's Standard Operating Procedure 2, the opinion below has been designated a precedential opinion.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MAREK Z. KUBIN and RAYMOND G. GOODWIN

Appeal 2007-0819
Application 09/667,859
Technology Center 1600

Decided: May 31, 2007

Before MICHAEL R. FLEMING, *Chief Administrative Patent Judge,* TEDDY S. GRON, TONI R. SCHEINER, ERIC GRIMES, and NANCY J. LINCK, *Administrative Patent Judges.*

LINCK, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a 35 U.S.C. § 134 appeal in the above-referenced case.[1]

We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] The application was filed September 20, 2000. The real party in interest is Immunex Corporation, a wholly owned subsidiary of Amgen Inc.

STATEMENT OF THE CASE

The field of the invention is polynucleotides encoding NK (natural killer) Cell Activation Inducing Ligand ("NAIL") polypeptides. (Specification ("Spec.") 1.) NK cells play a role in the "early, innate immune system" and "appear to be closely related to T cells." (*Id.*) Like T cells, the immune response of NK cells "involves direct cytotoxicity and production of various cytokines" that stimulate the immune system. (*Id.* at 3.)

"NK cells have been implicated as mediators of host defenses against infection in humans with varicella zoster, herpes simplex, cytomegalovirus, Epstein-Barr virus, hepatitis B, and hepatitis C viruses." (*Id.* at 3.) They also are "involved in both resistance to and control of cancer spread," including leukemia (*id.* at 3) and "play a . . . role in bone marrow transplant rejection, as well as solid organ transplant rejection." (*Id.* at 4.) Thus, "depletion of NK cells can result in a decreased resistance to target tissue infection by viruses." (*Id.* at 2.) Finally, "a number of human lymphoproliferative disorders of NK cells are known." (*Id.*) "With the function of NK cells so important in this variety of physiological responses, there is a need in the art for methods of controlling NK function." (*Id.*)

NAIL is a cell surface marker, or receptor, on the surface of NK cells that modulates the activity of NK cells. (*See id.* at 2.) Thus, modulation of NAIL activity would be expected to modulate NK cell function, thereby stimulating or inhibiting the immune response.

"CD48 is a membrane glycoprotein found on cells of hematopoietic origin." (*Id.* at 6.) "cDNA clones for CD48 have been isolated" and the

"nucleotide and amino acid sequences of CD48 are known." (*Id.*) Antibodies to CD48 appear to suppress cell mediated immunity. (*Id.* at 6-7.) "The identification of CD48 as a NAIL counter-structure . . . allows the generation of molecules that can modulate the activation of NK . . . cells." (*Id.* at 45.) Thus, the determination of binding to CD48 potentially provides a useful tool to identify active variants of NAIL. (*See, e.g.*, claim 73.)

The claimed subject matter is reflected in representative claim 73:[2]

73. An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48.

The Examiner has rejected claims 73-78 and 80-89 under 35 U.S.C. § 103(a) over the combined teachings of Valiante et al., U.S. Patent No. 5,688,690 (issued Nov. 18, 1997) ("Valiante"); Sambrook et al., *Molecular Cloning: A Laboratory Manual*, 2nd Edition, 2.43-2.84 (Cold Spring Harbor, N.Y. 1989) ("Sambrook");[3] and Porunelloor Mathew et al., *Cloning and Characterization of the 2B4 Gene Encoding a Molecule Associated with Non-MHC-Restricted Killing Mediated by Activated Natural Killer Cells and T Cells*, 151 J. IMMUNOL., 5328-5337 (1993) ("Mathew").[4]

The Examiner also has rejected claims 73, 74, 80, and 84-89 under 35 U.S.C. § 112, ¶ 1, for lack of enablement and written description.

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[2] Appellants do not separately argue the claims. Thus, we address each issue with reference to claim 73.

[3] We note Sambrook is incorporated by reference in Valiante (col. 7, ll. 55-57).

[4] This reference is referred to as "Porunelloor" by the Examiner and Appellants.

OBVIOUSNESS UNDER § 103(a)

The § 103(a) Issue

The Examiner contends the skilled artisan would have been motivated to isolate the nucleic acid sequence corresponding to NAIL, based on Valiante's disclosure of p38 (which is the same protein as NAIL) and Valiante's express teachings how to isolate p38 cDNA by using conventional techniques, such as taught in Sambrook, including using mAb C1.7, a probe specific for p38. (Answer 11-16.)

Appellants contend: "As in *Deuel*, it is not proper for the Office to use the p38 protein identified in the '690 patent [Valiante] together with the methods such as those described in Sambrook et al. to reject claims drawn to specific sequences." (Br. 19 (citing *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995).)

We frame the § 103(a) issue: Would Appellants' claimed nucleotide sequence have been obvious to one of ordinary skill in the art, based on Valiante's disclosure of p38 and his express teachings how to isolate its cDNA by conventional techniques?

Findings of Fact Relating to Obviousness

1. Valiante's p38 protein is a 38kd molecule recognized by mAb C1.7, and is the same protein as Appellants' NAIL, "formerly known as C1.7." (Spec. 10: 29-30. *See also* Answer 14; Spec. 11: 4.)

2. Valiante expressly teaches through a prophetic example how to "isolat[e] the cDNA clone by using [mAb] C1.7, screening the protein expression in the cell transfected with the cDNA library and cloning a corresponding cDNA into a plasmid for sequencing." (Answer 12 (citing Valiante, col. 7, l. 48 through col. 8, l. 7 & example 12, cols. 18-19).)

3. Valiante does not disclose the sequence of p38 recognized by mAb C1.7 or the DNA encoding p38. (*See* Valiante passim; Answer 12.)

4. The DNA and protein sequences of p38, and thus NAIL, could have been obtained by conventional methodologies, such as those taught by Sambrook. (Valiante, col. 7, l. 48 to col. 8, l. 7; *see also* Answer 12.)

5. Sambrook is incorporated by reference in Valiante. (Col. 7, ll. 55-57.)

6. Mathews' cell surface signaling molecule, 2B4, is the mouse version of Valiante's p38, the human version. (Answer 15.)

7. Mathews cloned the gene encoding 2B4 and determined its nucleotide sequence. (Mathews at 5328 (Abstract).)

8. The relevant teachings in Mathews are cumulative to the teachings in Valiante and Sambrook and merely are exemplary of how routine skill in the art can be utilized to clone and sequence the cDNA of a similar polypeptide. (*See* Answer 15.)

9. Appellants employed conventional methods, "such as those outlined in Sambrook," to isolate a cDNA encoding NAIL and determine the cDNA's full nucleotide sequence (SEQ NOS: 1 & 3). (Spec. 10: 29 to 13: 7; Spec. 16: 40 to 17: 1; Spec. 65 (Example 1).)

10. Appellants' claimed polynucleotide is "isolated from [a] cDNA library . . . using the commercial monoclonal antibody C1.7 . . . disclosed by Valiante." (Answer 13. *See also* Spec. 65: 17-32.)

11. As acknowledged by Appellants, "the level of skill in the art is high." (Br. 11 (citing *In re Wands*, 858 F.2d 731, 740, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).)

12. The state of the art had unquestionably advanced significantly during the ten year period between the time the *Deuel* application was filed in 1990 and Appellants' application was filed in 2000. *See In re Wallach*, 378 F.3d 1330, 1333, 71 USPQ2d 1939, 1942 (Fed. Cir. 2004).

13. As acknowledged by Appellants, "methods of making the claimed nucleic acid sequences . . . are known." (Br. 11 (citing *Wands*, 858 F.2d at 740). *See also* Br. 3 ("isolation of clones is well known in the art").)

14. Valiante's disclosure of the polypeptide p38, and a detailed method of isolating its DNA, including disclosure of a specific probe to do so, i.e., mAb C1.7, established Valiante's possession of p38's amino acid sequence and provided a reasonable expectation of success in obtaining a polynucleotide encoding p38, a polynucleotide within the scope of Appellants' claim 73. (*See* Valiante, col. 7, l. 48 to col. 8, l. 7.)

15. As recently clarified by the Federal Circuit, possession of the cDNA encoding NAIL also provided possession of its nucleic acid sequence, i.e., "its identity." *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004).

16. One of ordinary skill in the art would have had a reasonable likelihood of success that he or she would have been able to obtain the nucleotide encoding NAIL using conventional methods, such as disclosed in Valiante. (*See* col. 7, l. 48 to col. 8, l. 33.)

17. NAIL is "a signal transduction surface molecule (p38) expressed by virtually all human NK cells" and thus plays a role in the immune response. (Valiante, col. 2, l. 65 to col. 3, l. 40.)

18. Thus, one of ordinary skill in the art would have recognized the value of isolating NAIL cDNA, and would have been motivated to apply

conventional methodologies, such as those disclosed in Sambrook and utilized in Valiante, to do so. (*See, e.g.*, Valiante, col. 7, l. 48 to col. 8, l. 33.) *See Alza Corp. v. Mylan Labs*, 464 F.3d 1286, 1289, 80 USPQ2d 1001, 1003 (Fed. Cir. 2006) ("'The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.' *In re Gartside*, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1776 (Fed. Cir. 2000).").

Discussion of the § 103(a) Issue

Based on our findings and those of the Examiner, at least one of Appellants' claimed polynucleotides would have been obvious to one of ordinary skill in the art at the time Appellants' invention was made. Regardless of some factual similarities between *Deuel* and this case, *Deuel* is not controlling and thus does not stand in the way of our conclusion, given the increased level of skill in the art and the factual differences. *See In re Wallach*, 378 F.3d 1330, 1334, 71 USPQ2d 1939, 1942 (Fed. Cir. 2004) ("state of the art has developed [since] *In re Deuel*").

Appellants argue the "cited references do not provide an adequate written description of the claimed nucleic acid sequences." (Reply Br. 18 (citing *Noelle v. Lederman*, 355 F.3d 1343, 69 USPQ2d 1508 (Fed. Cir. 2004)). In so arguing, Appellants overlook the distinction between obviousness under § 103 and lack of written description under § 112, § 1. A single, obvious species within a claimed genus renders the claimed genus unpatentable under § 103. Thus, an obvious method of obtaining a single nucleic acid molecule encoding NAIL may be all that is required to show that the presently claimed genus of nucleic acid molecules is unpatentable under § 103. In contrast, as discussed *infra* (see pp. 15-17), the description

of a single species within a claimed genus may not be sufficient to support the patentability of the genus under § 112, ¶ 1. *See University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) (noting the court earlier held "a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention" and in this case holding disclosure of a species did not provide adequate written description of a genus). *Cf. Eli Lilly & Co. v. Barr Labs*, 251 F.2d 955, 971, 58 USPQ2d 1869, 1880 (Fed. Cir. 2001) ("later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim").

With respect to the written description requirement, while "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included "to demonstrate that the patentee possessed the full scope of the [claimed] invention." *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005). Thus, Appellants' argument based on alleged lack of written description in the cited prior art is unavailing.

Appellants heavily rely on *Deuel*. (*See, e.g.*, Br. 19.) To the extent *Deuel* is considered relevant to this case, we note the Supreme Court recently cast doubt on the viability of *Deuel* to the extent the Federal Circuit rejected an "obvious to try" test. *See KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, ___, 82 USPQ2d 1385, 1394, 1396 (2007) (citing *Deuel*, 51 F.3d at 1559). Under *KSR*, it's now apparent "obvious to try" may be an appropriate test in more situations than we previously contemplated.

When there is motivation

> to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007). This reasoning is applicable here. The "problem" facing those in the art was to isolate NAIL cDNA, and there were a limited number of methodologies available to do so. The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful. Thus, isolating NAIL cDNA was "the product not of innovation but of ordinary skill and common sense," leading us to conclude NAIL cDNA is not patentable as it would have been obvious to isolate it.

Appellants also argue lack of motivation to combine the cited references. (Br. 20-22; Reply Br. 19-21.) Motivation to combine references "may be found in implicit factors, such as 'knowledge of one of ordinary skill in the art, and [what] the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art'." *Alza Corp. v. Mylan Labs.*, 464 F.3d 1286, 1291, 80 USPQ2d 1001, 1004 (Fed. Cir. 2006) (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1337 (Fed. Cir. 2006)). *See also KSR*, 127 S. Ct. at ___, 82 USPQ2d at 1396 (citing with approval *In re Kahn*, 441 F.3d at 988, 78 USPQ2d at 1336).

More specifically, Appellants argue Mathews "teaches that a human homolog is not expressed," and thus "a person of skill in the art would not be motivated to combine" Mathews with Valiante. (Reply Br. 21.)

Appellants support this argument by quoting from Mathews: "Genomic Southern blots identified a human homologue of the 2B4 gene. However, RNA blot analysis of total RNA isolated from human NK cells suggests that 2B4 gene is not expressed in humans." (Mathews, at 5333, col. 1.)

Rather than teaching away from the combination, as Appellants argue, this language merely indicates conflicting data existed regarding a 2B4 homolog in humans, with some data pointing to the existence of a human homolog. (*See id.*) The quoted language would not have deterred the skilled artisan from obtaining the cDNA corresponding to Valiante's p38, as taught by Valiante, i.e., "from following the path set out in the reference." *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994), *quoted with approval in In re Kahn*, 441 F.3d 977, 990, 78 USPQ2d 1329, 1338 (Fed. Cir. 2006). Moreover, Appellants miscomprehend the value of Mathews. Mathews exemplifies how the cDNA encoding 2B4, the mouse version of Valiante's p38 expressed on all NK cells, can be isolated and sequenced. (*See* Mathews at 5328 (Abstract).) Thus, the teachings of Mathews, when considered as a whole, support the Examiner's § 103 ground of rejection.

PATENTABILITY UNDER § 112, ¶ 1

The Enablement Issue

The Examiner found lack of enablement due to the "at least 80% identity language," in the absence of any working examples, other than SEQ ID NOS:1 and 2. He cites examples in the literature in which very small changes in sequence, even one amino acid, yield a different function. (Answer 3-6.)

Appellants respond: "The Office's reasoning ignores the many references that positively demonstrate that proteins can be mutated and maintain a biological function." (Reply Br. 4 (citing numerous publications in support).) Moreover, "the specification provides extensive guidance for creating and screening mutants" (Reply Br. 5) in that it "teaches in detail how to: 1) make variants of SEQ ID NOs: 1 and 2; 2) calculate the percent identity between SEQ ID NOs: 1 and 2 and the variant sequence; and 3) test the variant sequence to determine if it binds to CD48" (Br. 11; Reply Br. 6). Thus, according to Appellants, only routine experimentation would be required to practice the claimed invention. (Reply Br. 9.)

In view of these conflicting positions, we frame the enablement issue as follows: Considering the relevant *Wands* factors, including the prior art teachings cited by the Examiner and Appellants to establish the level of predictability in the relevant art, would undue experimentation have been required to practice the full scope of claim 73?

The Written Description Issue

The Examiner bases his written description rejection on the same claim language as the enablement rejection, i.e., "at least 80% identity," and finds Appellants' disclosed sequences inadequate to show "possession of" their claimed genus. (Answer 9 (citing *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).)

In response, Appellants contend (1) *Lilly* can be distinguished on its facts and (2) the Examiner's position is inconsistent with Example 14 in the

Office's "Synopsis of Application of Written Description Guidelines"[5] (hereafter "*Synopsis*") (www.uspto.gov/web/patents/guides.htm), an example which contains "analysis of [a] claim that is highly similar to the claims at issue." (Reply Br. 13.)

In view of the above, we frame the written description issue: Does Appellants' Specification contain a written description sufficient to show they had possession of the full scope of their claimed invention at the time the application was filed, as required by Federal Circuit precedent?

Findings of Fact Relating to § 112, ¶ 1

19. Claim 73 is limited to isolated polynucleotides encoding polypeptides (1) which are "at least 80% identical to amino acids 22-221 of SEQ ID NO:2" (the amino acid sequence for the extracellular domain of NAIL without the signal sequence), and (2) which bind CD48. (*See* claim 73; Spec. 13: 9-18.)

20. The Specification provides two working examples within the scope of claim 73, i.e., a DNA encoding NAIL (SEQ ID NO: 1) and NAIL's coding sequence with accompanying upstream and downstream noncoding sequences (SEQ ID NO: 3). SEQ ID NOs: 1 and 3 both encode the amino acid sequence of SEQ ID NO: 2. (Spec. 10: 29 to 13: 7; Spec. 16: 40 to 17: 1; Spec. 65 (Example 1).)

21. The Specification also discloses the amino acid sequences for three fusion proteins (SEQ ID NOs: 6, 7, & 8) whose nucleotide sequences would fall within the scope of claim 73. (Spec. 25: 30 to 33: 9.)

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[5] Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan.5, 2001) ("*Written Description Guidelines*").

22. The Specification does not disclose any variants in which the nucleotide sequence encoding amino acids 22-221 of SEQ ID NO:2 is varied. (Spec. *passim.*)

23. Thus, the Specification does not disclose "which 20% . . . of amino acid residues should be changed in order to maintain the biological functions for binding to CD48." (Answer 5.)

24. The Specification "teaches in detail how to: 1) make variants of SEQ ID NOs: 1 and 2; 2) calculate the percent identity between SEQ ID NOs: 1 and 2 and the variant sequence; and 3) test the variant sequence to determine if it binds to CD48." (Br. 11; Reply Br. 6.)

25. The Specification does not disclose a correlation between function (binding to CD48) and structure responsible for binding to CD48 (other than the entire extracellular domain) such that the skilled artisan would have known what modifications could be made of the very large number of modifications potentially encompassed by claim 73 without losing function. (*See* Spec. *passim*; Answer 10.)

26. At the time Appellants' application was filed, molecular biology was generally an unpredictable art, as evidenced by the references cited by the Examiner. (Answer 4 (citing Robin E. Callard & Andy J.H. Gearing, The Cytokine FactsBook 188-89 (Academic Press 1994); Struyf et al., *Natural truncation of RANTES abolishes signaling through the CC chemokine receptors CCR1 and CCR3, impairs its chemotactic potency and generates a CC chemokine inhibitor*, 28 Eur. J. Immunol. 1262-71 (1998); & Proudfoot et al., U.S. Patent 6,159,711 (Dec. 12, 2000).)

27. At the time Appellants' application was filed, the level of skill in the relevant art (molecular biology) was high, as acknowledged by Appellants. (Br. 11.)

28. "[M]ethods of making the claimed nucleic acid sequences and screening for activity [were] known in the art and described in the specification." (Br. 11-12.)

29. The "experimentation involved to produce other sequences within the scope of the claims" and thus to practice the full scope of claim 73, would have been "well within the skill of those in the art" (Br. 12) and thus would have been routine.

30. One of ordinary skill in the art would not have been required to perform undue experimentation to practice the invention of claim 73.

Discussion of the Enablement Issue

In making the above findings, we have considered the relevant *Wands* factors in light of the prior art teachings relied upon by the Examiner and Appellants, and the relevant caselaw. We agree with the Examiner that molecular biology is generally an unpredictable art (and thus was so at the time the application was filed). However, with respect to enablement, the other *Wands* factors weigh in Appellants' favor, particularly "the state of the art" and "the relative skill of those in the art," *In re Wands*, 858 F.2d 731, 736, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), as evidenced by the prior art teachings and Appellants' Specification.

The amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine. The techniques necessary to do so were well known to those skilled in the art. *See, e.g., Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342,

1360, 47 USPQ2d 1705, 1719 (Fed. Cir. 1998) ("test [for undue experimentation] is not merely quantitative . . . if it is merely routine"). A "patent need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). Thus, we conclude the Specification would have enabled the full scope of claim 73.

Discussion of the Written Description Issue

In spite of concluding claim 73 would have been enabled, Federal Circuit caselaw compels us to find the written description requirement is not met. *See generally, e.g., University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004); *Enzo Biochem. Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 63 USPQ2d 1609 (Fed. Cir. 2002); *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997); *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993).

"Although there is often significant overlap" between the enablement and written description requirements, "they are nonetheless independent of each other." *University of Rochester*, 358 F.3d at 921, 69 USPQ2d at 1891. An "invention may be enabled even though it has not been described." *Id.* Such is the situation here. While we conclude one skilled in the art would have been able to make and use the full scope of claim 73 through routine experimentation, we find Appellants did not describe the invention of claim 73 sufficiently to show they had possession of the claimed genus of nucleic acids. *See, e.g., Noelle v. Lederman*, 355 F.3d 1343, 1348, 69 USPQ2d 1508, 1513 (Fed. Cir. 2004) ("invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*").

Claim 73 is to a genus of polynucleotides encoding polypeptides "at least 80% identical to amino acids 22-221 of SEQ ID NO:2" which bind to CD48. Sufficient description to show possession of such a genus "may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

In this case, Appellants have sequenced two nucleic acids falling within the scope of claim 73 and three fusion proteins whose nucleotide sequences would fall within the scope of claim 73. None of these sequences varies amino acids 22-221 of NAIL, and thus these sequences are not representative of the genus.

Appellants also have described how to make and test other sequences within claim 73 sufficiently to satisfy the enablement requirement. However, they have not described what domains of those sequences are correlated with the required binding to CD48, and thus have not described which of NAIL's amino acids can be varied and still maintain binding. Thus, under *Lilly* and its progeny, their Specification would not have shown possession of a sufficient number of sequences falling within their potentially large genus to establish possession of their claimed genus. *Cf. Enzo*, 323 F.3d at 964, 63 USPQ2d at 1612 ("if the functional characteristic of . . . binding to [CD48] were coupled with a disclosed correlation between

that function and a structure that is sufficiently known or disclosed," the written description requirement may be met).

Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 ("definition by function ... does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is").

With respect to Appellants' reliance on hypothetical Example 14 in the Office's *Synopsis*, "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (quoting *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971)), *quoted with approval in Enzo*, 323 F.3d at 963, 63 USPQ2d at 1612. While the *Written Description Guidelines* and the hypothetical examples in the Office's *Synopsis* can be helpful in understanding how to apply the relevant law (as it existed in 2001 when the Guidelines were adopted), they do not create a rigid test.

Based on the above, we find the written description requirement of § 112, ¶ 1, is not met.

CONCLUSION

In summary, with respect to claim 73, we affirm the § 103(a) rejection, reverse the § 112, ¶ 1, enablement rejection, and affirm the § 112, ¶ 1, written description rejection.

Pursuant to § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 74-78 and 80-89 under § 103(a); reverse the § 112, ¶ 1, enablement rejection of claims 74, 80, and 84-89; and affirm the § 112, ¶ 1, written description rejection of claims 74, 80, and 84-89, as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

dm

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1The opinion in support of the decision being entered today is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MAREK Z. KUBIN and RAYMOND G. GOODWIN

Appeal 2007-0819
Application 09/667,859
Technology Center 1600

Decided: October 24, 2007

Before MICHAEL R. FLEMING, *Chief Administrative Patent Judge,* TEDDY S. GRON, TONI R. SCHEINER, ERIC GRIMES, and NANCY J. LINCK, *Administrative Patent Judges.*

LINCK, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING

Pursuant to 37 C.F.R. § 41.52, Appellants request rehearing and reversal of the Board's May 31, 2007 Decision on Appeal ("Decision")[1] with respect to the Board's obviousness and written description determinations (Request for Rehearing Pursuant to 37 C.F.R. § 41.52 ("Request")). We

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[1] The Decision has been designated "Precedential."

have reconsidered the decision pursuant to 35 U.S.C. § 6(b) and 37 C.F.R. § 41.52 on the points specifically raised in the request; and

DENY the requested relief.

DISCUSSION

Appellants argue five points on which they believe rehearing should be granted. According to Appellants, our Decision —

1. is inconsistent with *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007);

2. "overlooked or misapprehended the state of the prior art," "misapprehended" Mathew's teachings, and "incorrectly dismissed the compelling 'teaching away' evidence of Mathew";

3. inappropriately failed to enter a new ground of rejection, if the Decision did not rely on Mathew and instead was based solely on Valiente and Sambrook;

4. "erroneously stated that Appellants did not separately argue the claims"; and

5. "overlooked or misapprehended . . . the state of the art," as to the written description rejection (Request 1-4).

We have carefully considered Appellants' arguments and conclude they have not established that the Board's Decision should be modified.

Takeda was decided after our Decision. Moreover, *Takeda* is factually dissimilar, and, in any case, does not take any position contrary to those expressed in the Board's Decision.

Second, Appellants have not shown that the Board overlooked or misapprehended the state of the prior art or Mathew's teachings in any

significant regard. The relevant art, including Mathew, was carefully analyzed, and appropriate factual findings[2] were made (Decision 4-7 (FF 1-18)).

Third, Appellants have not shown that the Board was required to enter a new ground of rejection. The Board found Mathew's teachings were cumulative (*id.* at 5 (FF 8)). The rejection remains under § 103(a), based on the same references relied upon by the Examiner. Appellants had a full and fair opportunity to respond to the Valiente and Sambrook teachings. *See In re Kronig*, 539 F.2d 1300, 1302 (CCPA 1976) ("the ultimate criterion of whether a rejection is considered 'new' in a decision by the board is whether appellants have had fair opportunity to react to the thrust of the rejection").

Fourth, Appellants have not shown the Board erred in finding that the claims were not argued separately, pursuant to 37 C.F.R. § 41.37(c)(1)(vii). "A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim." *Id.* Arguments such as the "remainder of the Claims have separate and distinct limitations and must be considered independently" (Appeal Br.[3] 5) do not meet the requirements of the Rules. Appellants have not established that language such as "[t]he cited references, alone or in combination, fail to teach a single nucleic acid molecule encoding a polypeptide at least 80% or 90% identical to SEQ ID NO:2 as required by Claims 73, 74, and 84-89, much less the specific nucleic acid sequences specified in the remainder of the claims" (Appeal Br. 18) and "the Office failed to present any evidence that the cited references teach the 80% identity limitation of Claims 73, 80 and 84-89, the 90% identity limitation of Claim 74, or the specific sequences

[2] Findings of Fact are abbreviated "FF."
[3] Appellants' Brief (filed Sept. 24, 2003).

[of] Claims 75-78 and 81-83" (*id.* at 20) supports Appellants' position. The Board fairly exercised its discretion in selecting claim 73 as representative (*see* 37 C.F.R. § 41.37(c)(1)(vii)).

Finally, Appellants have not shown that the Board overlooked or misapprehended the state of the prior art with respect to the written description rejection (*see* Decision 12-14 (FF 19-30) & 13-17 (reasoning supporting the Board's finding that "Appellants did not describe the invention of claim 73 sufficiently to show they had possession of the claimed genus of nucleic acids" (*id.* at 15))).

CONCLUSION

The request for rehearing has been considered, but relief on the merits is—

DENIED

dm

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